

REMARKS

Withdrawn Claims and Cancelled Claims

Claims 21-41 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has chosen to maintain the remainder of the withdrawn claims 21-41 in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

Claim Rejections – 35 USC §102 and 103

Claims 1 and 58-60 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,397,364 to Kozak et al. (hereafter “the Kozak patent”), and claims 1, 58-60, 63-65, 68 and 69 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,192,327 to Brantigan (hereafter “the Brantigan patent”). Additionally, claims 1-10, 12, 13, 17-18, 58, 59, 64 and 69 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,514,180 to Heggeness (hereafter “the Heggeness patent”).

Further, claims 14-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Heggeness patent in view of U.S. Patent No. 4,703,108 to Silver et al. Also, claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over the Heggeness patent in view of U.S. Patent No. 5,366,875 to Wozney et al., and claims 19, 20, 60-63 and 65-68 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Heggeness patent in view of U.S. Patent No. 5,609,635 to Michelson.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

As set forth on pages 2 and 4 of the Office Action, an assertion is made that the claims do not distinguish over the art of record because the claim “fails to specifically define the flat lateral surface as extending continuously from the anterior to the posterior wall” and that “[a]s broadly worded, the flat lateral surface may be interpreted as extending in the plane perpendicular to the AP plane”. To address these assertions, the Applicant has amended each

of the independent claims 1 and 58 to recite that the lateral walls each have “a flat lateral surface extending continuously from said anterior wall to said posterior wall to define a chamber”. Additionally, as set forth on pages 3 and 4 of the Office Action, an assertion is made that the claims do not distinguish over the Kozak patent because the claim “fails to define the device as a monolithic body”, and that “[t]he body of Kazak is an integral single piece body as broadly claimed. Note the claim does not define the body as a monolithic body”. To address these assertions, the Applicant has amended each of the independent claims 1 and 58 to recite that the two lateral walls and the anterior and posterior walls are integral “to define a monolithic, single-piece spacer body”.

With regard to the Kozak patent, the interbody fusion device 20 does not include an anterior wall having a convexly curved anterior surface, an opposite posterior wall having a flat posterior surface, and two lateral walls each having “a flat lateral surface extending continuously from said anterior wall to said posterior wall to define a chamber”, as recited in independent claims 1 and 58. Even assuming arguendo that the anterior spacer portion 23 defines a convexly curved anterior surface and the posterior spacer portion 22 defines a flat posterior surface, each of the lateral spacer portions 21 clearly do not define “a flat lateral surface extending continuously between said opposite ends of said anterior and posterior walls”. Indeed, the lateral walls of the fusion device 20 are convexly curved in the AP plane. Notably, the assertion set forth in the Office Action that “the lateral walls are flat in the direction perpendicular to the AP plane” is obviated in view of the amendments incorporated into independent claims 1 and 58 that the lateral walls each have a flat lateral surface extending continuously from the anterior to the posterior wall.

Furthermore, the anterior, posterior and lateral portions of the fusion device 20 do not cooperate to define “a D-shaped spacer body”, as also recited in independent claims 1 and 58. To the contrary, the fusion device 20 has a kidney bean shape. Moreover, the anterior and posterior spacer portions 22, 23 of the fusion device 20 are not formed integral with the lateral spacer portions 21 “to define a monolithic, single-piece spacer body”, as further recited in independent claims 1 and 58. To the contrary, the fusion device 20 comprises a multi-piece structure, with the anterior, posterior and lateral portions sized for individual and percutaneous introduction into the disc space, and with the spacer portions subsequently

assembled within the disc space to form the assembled multi-piece fusion device 20. (See e.g., Abstract and column 5, lines 10-21).

For at least these reasons, the Applicant submits that the Kozak patent does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the Kozak patent and requests allowance of the same.

With regard to the Brantingan patent, even assuming arguendo that the hemi-oval device 20 illustrated in Figure 2 includes a first wall having a convexly curved surface, an opposite second wall having a flat surface, and two lateral walls each having a flat surface, with each of the walls cooperating to define a D-shaped spacer body, the hemi-oval device 20 still fails to satisfy important structural features recited in independent claims 1 and 58. Specifically, the hemi-oval device 20 is not “sized and configured to substantially fill the space between the vertebrae”, as recited in each of the amended independent claims 1 and 58. To the contrary, the hemi-oval device 20 is sized and configured to fill no more than one-half of the disc space. Indeed, a pair of the hemi-oval devices 20 positioned side-by-side are required to substantially fill the disc space. Moreover, the convexly curved surface of the hemi-oval device 20 is not “sized and shaped to substantially conform to an anterior aspect of the space between the vertebrae”, nor are the walls of the hemi-oval device 20 “sized and shaped such that a single spacer body is sufficient to preserve a height of the space between the vertebrae”, as also recited in each of the amended independent claims 1 and 58. Instead, the convexly curved surface of the hemi-oval device 20 has a relatively tight radius of curvature that is sized and shaped to conform to a lateral aspect of the disc space, and which clearly would not conform to an anterior aspect of the disc space within which the device 20 is inserted. Furthermore, the walls hemi-oval device 20 are sized and shaped such that a pair of the hemi-oval device 20 positioned side-by-side are required to preserve a height of the space between the vertebrae.

As should be appreciated, the particular size and shape of the spacer body recited independent claims 1 and 58 is an important aspect of the claimed invention in that such a configuration allows use of a single spacer to support the adjacent vertebrae, while at the

same time inhibiting subsidence into the softer cancellous bone of the adjacent vertebrae. As indicated on page 8, lines 12-14 of the present application, the curved anterior wall conforms to the harder cortical bone of the adjacent vertebral bodies, thereby inhibiting subsidence into the softer inner cancellous bone. Additionally, the relatively larger size and shape of the implant recited in independent claims 1 and 58 provides advantages over the much smaller hemi-oval device 20 disclosed in the Brantigan patent. Specifically, a pair of the hemi-oval devices 20 would have to be positioned side-by-side and engaged with one another to substantially fill the disc space. However, the size and shape of the spacer recited in independent claims 1 and 58 is such that a single spacer may be utilized to support substantially the entire space between adjacent vertebrae.

For at least these reasons, the Applicant submits that the Brantigan patent does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the Brantigan patent and requests allowance of the same.

With regard to the Heggeness patent, the device 70 illustrated in Figure 24 does not include an anterior wall having a convexly curved anterior surface, an opposite posterior wall having a flat posterior surface, and two lateral walls each having “a flat lateral surface extending continuously from said anterior wall to said posterior wall to define a chamber”, as recited in independent claims 1 and 58. Even assuming *arguendo* that the anterior portion of the outer ring 72 defines a convexly curved anterior surface and that the posterior portion defines a flat posterior surface, each of the lateral portions of the outer ring 72 clearly do not define “a flat lateral surface extending continuously between said opposite ends of said anterior and posterior walls”. To the contrary, the lateral portions of the outer ring 72 extending between the anterior and posterior walls in the AP plane are clearly convexly curved. Indeed, virtually the entire device 70 is formed by curved wall portions. Notably, the assertion set forth in the Office Action that “the lateral walls are flat in the direction perpendicular to the AP plane” is obviated in view of the amendments incorporated into each of the independent claims 1 and 58. Furthermore, the anterior, posterior and lateral portions of the spacer device 70 do not cooperate to define “a D-shaped spacer body”, as also recited

in independent claims 1 and 58. To the contrary, the spacer device 70 has a kidney bean shape.

For at least these reasons, the Applicant submits that the Heggeness patent to Heggeness et al. does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the Heggeness patent and requests allowance of the same.

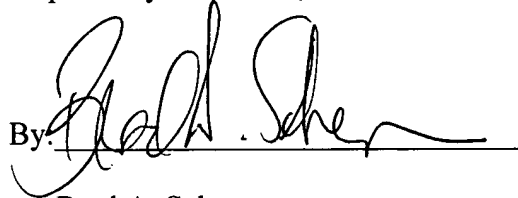
Dependent claims 2-20 and 59-64 depend either directly or indirectly from amended independent claim 1 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 1. Additionally, dependent claims 65-69 depend either directly or indirectly from amended independent claim 58 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 58.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1-20 and 58-69.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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